Routine Perinatal Testing The Opt-Out Approach Questions and Answers

Why does CDC recommend making HIV screening a part of the routine battery of prenatal testing for all pregnant women?

The timely administration of a potent combination of antiretroviral drugs during pregnancy can reduce the risk of mother-to-child HIV transmission to 2 percent or less, and also improve the health of the mother. But, first the pregnant woman's HIV status must be known.

Although CDC has recommended voluntary HIV testing for all pregnant women since 1995, new data show that prenatal HIV screening rates continue to vary greatly based on the testing approaches used. Higher prenatal screening rates were reported for states that used a strategy of opt-out HIV screening (routine testing will be done as part of the standard battery of tests for all pregnant women, unless the woman declines testing) or mandatory testing of newborns when the mother's HIV status is unknown.

Is mother-to-child HIV transmission a big problem?

Yes. Approximately 6,000 to 7,000 HIV-infected women gave birth in the United States in the year 2000, and without knowing their status and receiving interventions, one in four of their babies would have been infected. In 2000, an estimated 280-370 HIV-infected infants were born in the U.S. Worldwide the problem is even larger with 1,600 babies infected each day and over half a million babies infected each year by mother-to- infant transmission of HIV.

What approaches to prenatal testing are currently used in the United States?

- "Opt-out": Pregnant women are notified that an HIV test will be routinely included in the standard battery of prenatal tests for all pregnant women, unless they decline HIV testing. This is the current standard recommended by the CDC.

- "Opt-in": Pregnant women are provided with pre-HIV test counseling and must specifically consent to an HIV antibody test, usually in writing.

- In addition, in cases where the mother's HIV status is unknown at delivery, some states mandate that newborns be tested for maternal HIV-antibody, with or without the mother's consent, if the mother's HIV status is unknown at delivery. Results must be available within 12 hours of birth in New York and within 48 hours in Connecticut, the two states that have implemented this approach.

What are some of the advantages of routine prenatal testing with the right to decline-- the opt-out approach?

The opt-out approach is expected to substantially increase testing rates among pregnant women, based on new information from the U.S., Canada, Europe, and Africa. This approach should increase the proportion of HIV-infected women who are offered appropriate antiretroviral and obstetrical interventions to prevent perinatal HIV transmission and to protect the woman's own health.

Data indicate that women are more likely to accept testing when it is offered and recommended by their prenatal care providers. But some providers continue to find requirements for extensive pre-test counseling and consent documentation to be barriers to offering the test. The opt-out approach is designed to reduce those barriers while preserving the voluntary nature of testing and increasing the opportunity for all pregnant women to have HIV screening.

How would the opt-out approach be implemented?

The simplest approach requires notifying the pregnant woman that an HIV test is performed as part of the standard battery of prenatal tests, but that the woman can decline the test — with documentation of her refusal in the medical chart. Another approach might be to document a pregnant woman's consent for the routine battery of prenatal tests, including HIV screening, and, if she declines HIV testing, to document this in her medical chart. CDC recommends that pregnant women, at minimum, be given a brochure on prevention of perinatal HIV transmission and treatment of maternal HIV.

What data support the use of the opt-out approach?

In the November 15, 2002, *Morbidity and Mortality Weekly Report,* CDC published information on the most recently available prenatal HIV testing rates in the United States and Canada. The report looked at HIV prenatal testing rates associated with different testing approaches.

Among states using the opt-in approach where data were collected from medical records from 1998-1999, testing rates ranged from 25-69 percent. Population-based data from Canada showed testing rates in three opt-in provinces of 54-83 percent. In contrast, medical record data from Tennessee, which uses an opt-out approach, indicated a testing rate of 85 percent. Canadian data from provinces using opt-out approaches showed a 98 percent testing rate in Alberta and a 94 percent testing rate in Newfoundland and Labrador.

In addition to these findings, several other recent publications and presentations support the use of opt-out as a method that achieves high prenatal HIV screening rates. These include a report from Birmingham, Alabama, and a recent presentation at the 10th Retrovirus conference based on experience at four sites in Kenya.

Why is CDC recommending routine HIV testing in labor and delivery for women with unknown HIV status?

Early identification of HIV infection clearly affords the best opportunity for perinatal HIV prevention. However, when interventions cannot be offered until labor or delivery or to the newborn, transmission rates of 9-13 percent have been seen in clinical trials and observational studies. These transmission rates compare with a <2% transmission rate achievable when interventions are delivered during pregnancy and approximately a 25% transmission rate when no effective combination antiretrovirals are given.

What is CDC's recommendation for HIV testing in labor and delivery?

When a woman's HIV status is unknown at labor, CDC recommends opt-out, rapid HIV testing. Rapid HIV test kits have been approved by the U.S. Food and Drug Administration and can be used at point of care in labor and delivery. Results of rapid HIV testing can be available in as little as 20 minutes.

When rapid tests are positive, antiretroviral interventions can be offered to the mother during labor, and to her infant based on the preliminary results. Confirmatory testing should occur as soon as possible. CDC has developed a model rapid testing protocol for use at labor and delivery, which is available at CDC's website at http://www.cdc.gov/hiv/rapid_testing/materials/Labor&DeliveryRapidTesting.pdf

Who should be given rapid HIV testing?

Every woman who presents in labor without a documented HIV test result should be given a rapid HIV test, with the option to decline.

Does consent need to be obtained to do rapid HIV testing in labor?

The woman should be informed that HIV screening is routinely done at labor or delivery whenever a woman does not have the documented results of an HIV test performed during her pregnancy or documentation of HIV infection from the time during or before her pregnancy. She should be further informed that the test is voluntary and can be declined.

Do these new recommendations conflict with CDC's previous recommendations for counseling and testing of pregnant women?

These recommendations are consistent with the guidelines of the November 2001 "Revised Recommendations for HIV Screening of Pregnant Women." The report recommended simplifying and removing barriers to prenatal screening, and HIV screening at labor/delivery for women whose HIV status is unknown.

Where is more information available?

For more detailed information on the "Revised Recommendations for HIV Screening of Pregnant Women," please refer to *Morbidity and Mortality Weekly Report* (MMWR) of November 9, 2001, at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm.

Request a hard copy from the National Prevention Information Network at (800) 458-5231.

For information on prenatal screening rates with different testing approaches, please refer to the November 15, 2002, MMWR, "HIV testing among pregnant women—United States and Canada, 1998-2001," at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5145a1.htm

Additional information is also available in CDC's notice to readers in MMWR issue 10 on March 14, 2003, at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5210a7.htm